

App. Ser. No. 10/051,459 Attv. Dkt. No. 010743.50685US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.

10/051,459

Confirmation No.: 6980

Applicant

: Hans BEER, et al.

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Customer No.

: 23911

Title

: SURFACE-ENHANCED MEMBRANE AND PROCESS

AND APPARATUS FOR PRODUCING SAME

DECLARATION UNDER 37 C,F,R. § 1.132

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

I, Dr. Hans Beer, declare that:

- 1. I am a resident and citizen of Germany. I am the inventor of the invention described in the above-referenced application.
- 2. I have a doctor's degree of natural science and 34 years of experience in the field of membrane technology. My current job title at Sartorious AG is Senior Scientist in the research & development department of membrane technology.
- 3. In my Declaration dated February 2, 2006, I described (i) the present invention, an improved process for refining the surface of a membrane, and a resulting membrane used to identify specific analytes present in fluid media (the invention involving removal of impurities after the membrane is formed, but before the newly-formed membrane dries, by contacting the still-wet membrane

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with a cleaning agent and/or a cleaning device), (ii) the prior art problems with filter dust particles formed on membrane structures even with measures such as filtration and/or precipitation of impurities from the filter feedstock liquids, (iii) the lack of suggestion in the prior art for removal of impurities after formation of the membrane, but before all the solvent as been evaporated, and (iv) why the removal of contaminants prior to drying a feedstock was not merely the result of "optimization of a result effective variable."

- 4. I am aware that in the U.S. Office Action mailed April 28, 2006, the Examiner indicated that the provision of further information showing actual data reflecting the unexpected results of the present invention may be sufficient to demonstrate the results are not a matter of optimization. The following information documents the testing conducted to provide the desired demonstration.
- 5. The attached table, Attachment 1, identifies the testing procedure used to prepare the filter membrane samples shown in the enclosed test result photographs, Fig. 1 (prior art) and Fig. 2 (present invention). As shown in the table, the membrane preparation process started with refinement of the cellulose nitrate raw feedstock material for the membrane prepared with the prior art U.S. Patent No. 5,628,960 process (the Fig. 1 membrane). Importantly, as shown in the table, the feedstock material for the present invention membrane (the Fig. 2 membrane) was not refined, consistent with the present invention's ability

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to provide unexpectedly good results without the need for the prior art feedstock material refinement.

- 6. The next membrane preparation step was preparation of the casting dope for each membrane, according to the standard procedures of Sartorius AG, from the refined feedstock material (Fig. 1 membrane) and the unrefined feedstock material (Fig. 2 membrane). As shown in the third row of information in the Attachment 1 table, the casting dope composition of the two membrane samples differed only in the use of refined v. unrefined feedstock materials, otherwise having numerically identical ratios of CN components, methyl acetate, isopropanol, cellulose acetate, sodium alkyl sulfonate and water.
- 7. The refined and unrefined casting dope samples were then cast in an identical manner by an evaporation process using on a 100 µm polyethylene terephthalate film support, with identical wet film thickness, environmental conditions and belt temperature and speed.
- 8. In the final steps, consistent with my patent application description and claim 1 of the application (U.S. application Ser. No. 10/051,469), prior to drying the Fig. 2 membrane, filter dust was removed from the upper surface of the Fig. 2 membrane by mechanical treatment with a rotating brush under controlled water rinsing and application of diluted sodium alkyl sulfonate. Both membranes were then finally dried under standard conditions.
- 9. The filter membrane test strips were subjected to a migration test with a phenol red test liquid. The Fig. 1 membrane, having a pore size of 8 µm had a

migration time of about 130 sec/40 mm, and provided a relatively poor quality (as compared to the present invention) test line, which was diffuse and had a substantially non-uniform dividing line. Such a test line greatly increases the difficulty in exactly determining test substances in actual testing work. The Fig. 2 membrane, also having a pore size of 8 µm, was subjected to the same migration test with a phenol red test liquid, and also demonstrated a migration time of about 130 sec/40 mm. The Fig. 2 photograph shows markedly superior results, despite the lack of pre-casting feedstock refinement, over the prior art Fig. 1 membrane, with the test line demonstrating a significantly more precise and uniform dividing line.

10. This testing demonstrates the unexpectedly superior results provided by a membrane prepared in accordance with the present invention, which enables exact determination of test substances to a degree not possible with a membrane prepared with prior art refined feedstock membranes.

I declare that the preceding statements which are made from my own knowledge are true and that the preceding statements which are made on information and belief are believed to be true.

I am aware that willful false statements and the like are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States

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Code and may jeopardize the validity of the application or any patent issuing thereon.

DATE

Dr. Hans Beer

Description of Membrane Sample Preparation

No. 1980	Membrane sample	
	corresponding to	
Preparation step	Fig. 1 (U. S. patent no. 5.628,960)	Fig. 2 (U.S.application no. 10/ 051,459)
refinement of cellulose nitrate raw materials	yes	no
	 dissolution of the CN components in methyl acetate, reprecitation with Isopropanol/ water filtration drying 	
preparation of casting dops	- from refined CN raw materials	- from original, not refined CN raw materials
	according to our standard operation procedure (including e.g sequence of addition - temperature, - stirring time & speed and so on)	according to our standard operation procedure (including e. g sequence of addition - temperature, - stiming time & speed and so on)
casting dope composition	- numerically I	dentical ratios,
	- consisting of - CN components - methyl acetate - isopropanol - cellulose acetate - sodium alkyl sulfonate - water - identical qualities of all components with exception of cellulose nitrate refined / resp. not refined	
casting process	casting on a 100 µm polyethylene terephthalate film support	
casung process	casting on a 100 µm polyethylene telephthalate film support under defined, identical conditions, concerning e. g: -wet film thickness - belt temperature and speed - climatic conditions inside the casting channel	

Removal of filter dust	no	yes , by
		- mechanical treatment of the upside of the membrane with a rotation brush under rinsing with water at defined conditions - reimpregnation with diluted sodium alkyl sulfonate
final drying	with standard production equipment under defined standard conditions	

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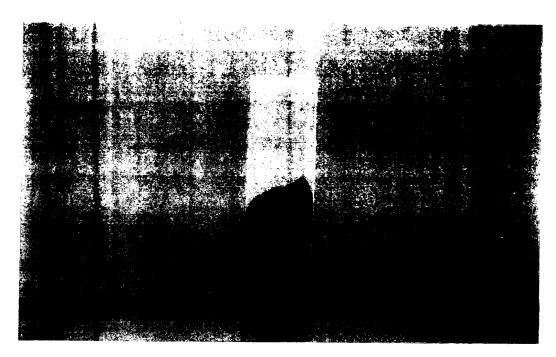


Fig. 1

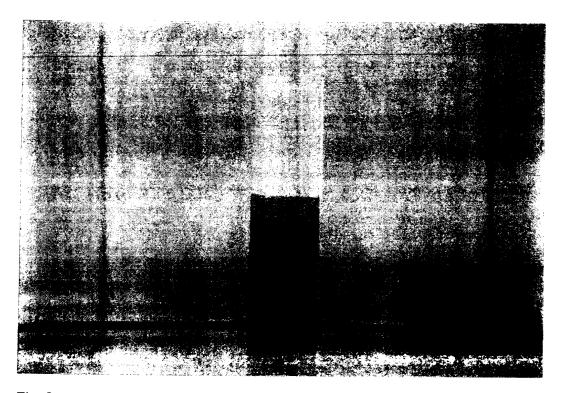


Fig. 2